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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,420	08/15/2006	Tsukao Yokoyama	YPO1.001APC	9866

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

GRUN, JAMES LESLIE

ART UNIT	PAPER NUMBER
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1641

NOTIFICATION DATE	DELIVERY MODE
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04/12/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
efiling@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No. 10/589,420	Applicant(s) YOKOYAMA ET AL.	
	Examiner JAMES L. GRUN	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21,26-30,32,33 and 35-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21,26,28-30,32,33,35 and 36 is/are allowed.
- 6) ☒ Claim(s) 27 is/are rejected.
- 7) ☒ Claim(s) 37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The amendment filed 24 January 2011 is acknowledged and has been entered. Claims 1-20, 22-25, 31, and 34 have been cancelled. Claims 21, 26-30, 32, 33, and 35-37 remain in the case.

Applicant's prior showing of the current ready commercial availability of the "NC1" antibody was sufficient to overcome a prior deposit requirement made in a previous Office action. Applicant is cautioned that the material required for practice of the method may cease to be known and readily available to the public at some future time. Public access during the term of a patent may affect the enforceability of that patent.

The declaration of co-inventor Tsukao Yokoyama under 37 CFR 1.132, filed 24 January 2011, is sufficient to overcome the prior rejection of the claims based upon the insufficiency of the disclosure for early disease indication under the enablement provisions of 35 U.S.C. 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

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Claim 27 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth, absent further description and guidance from applicant, one would have no assurance of practicing the method as claimed because one would not be able to apply a method taught as suitable for fluid samples to a frozen tissue sample as is now claimed.

Applicant's arguments filed 24 January 2011 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, the issue is not whether applicant's specification provides support for an ELISA, the issue was and is, as set forth, whether applicant's specification provides sufficient description and enablement for one to predictably use an ELISA (i.e., enzyme-linked immunosorbent assay (emphasis added)) taught for liquid samples to detect antigen in a frozen tissue sample as now claimed. The rejection is maintained for the reasons of record. The examiner would suggest --enzyme-linked immunoassay-- or --enzyme immunoassay-- or --immunoenzymatic assay--, or other variation thereof, rather than an "ELISA" which applicant teaches for liquid samples, not a tissue sample as claimed.

Claim 37 is objected to because of the following informalities: the claim fails to end in a period. Appropriate correction is required.

Claims 21, 26, 28-30, 32, 33, 35, and 36 are currently free of the prior art of record and are allowable.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Yokoyama et al. (Cell 35: 40, 2003), in light of the translation made of record, teach enzyme-linked immunosorbent immunoassays for the detection of circulating noncollagenous domain of collagen (NC1) antigen and antibodies specific for NC1 antigen in biological samples from patients with and without nephritis. Antigen and antibody detection is taught for the determination of early stage glomerulonephritis or a risk therefor. Levels of antigen and antibody were determined in both serum and urine samples. Urine samples are considered herein as a sample derived from kidney. The reference also teaches that an improvement of dialysis therapy would involve the removal of NC1 antigen and antibodies specific for NC1 antigen from the glomerulonephritis patient during dialysis (see e.g. translation pages 7 and 8).

The Cosmo Bio Co. Ltd. references teach the commercial availability of the K35MONO anti-NC1 monoclonal antibody, which, absent evidence to the contrary, is identical to applicant's NC1 monoclonal antibody, Mono 12D, in view of applicant's specification at page 12.

Oftshun et al. (US 5,871,649) teach an affinity membrane device in a columnar shape for the removal of deleterious solutes such as autoantibodies in the blood of Goodpasture's syndrome patients (see e.g. col. 19).

Sugihara et al. (J. Pathol. 178: 352, 1996) teach anti-NC1 autoantibodies in the blood of patients with Goodpasture's syndrome, an anti-glomerular basement membrane antibody-induced glomerulonephritis autoimmune disease. The reference teaches at least one anti-NC1 monoclonal antibody.

Johansson et al. (J. Biol. Chem. 267: 24533, 1992) provided monoclonal and polyclonal antibodies to bovine glomerular basement membrane NC1 and used the antibodies in ELISA, Western blotting reactions, and in affinity columns for purification of NC1. In the ELISA, immobilized NC1 was used to capture the antibodies (an anti-NC1 antibody remover). The reference teaches populations of noncollagenous domains of collagen (NC1) in glomerular basement membranes.

Ninomiya et al. (J. Cell Biol. 130: 1219, 1995) teach monoclonal antibodies specific for NC1 peptides and their use in various immunoassays.

Borza et al. (J. Biol. Chem. 276: 28532, 2001) elicited monoclonal antibodies to bovine glomerular basement membrane that bound to NC1 in ELISA and were also used in Western blotting reactions. The antibodies were used in affinity columns for purification of NC1 (a NC1 remover) and were used in immunoprecipitation assays with protein G-sepharose (an anti-NC1 antibody remover).

Yokoyama et al. (Cell 34: 36, 2002) teach induction of glomerulonephritis by injection of the NC1 domain of type IV collagen. The submitted translation is incomplete, however, and it is not clear if immunofluorescent immunohistochemical assays were used to detect glomerulonephritis.

Lan et al. (Clin. Exp. Immunol. 110: 233, 1997) teach glomerular crescent formation as an indicator of severe glomerular damage and disease.

Campbell teaches the general procedure for the production of monoclonal antibodies (pages 3-6) and that substituting a monoclonal antibody for a polyclonal antibody in an established immunoassay “is not novel and is obvious” (page 45).

Kitchell et al. (US 5,656,298) teach immunization with a primer dose and a delayed release booster dose five times that of the primer dose (see e.g. col. 14 and Fig. 7).

Chambers et al. (US 6,696,281) teach immunization with a primer dose and boosting with a higher dose than that of the primer dose for vaccination (see e.g. col. 62, Table 8).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE

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ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 11 a.m. to 7 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, SPE, can be contacted at (571) 272-0806.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J. L. G./

James L. Grun, Ph.D.

Examiner, Art Unit 1641

April 8, 2011

/Shafiqul Haq/

Primary Examiner, Art Unit 1641